





## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/824,567 04/03/2001		Andrew D. Murdin	032931/0246	9703	
75	990 08/07/2002				
	Bernhard D. Saxe FOLEY & LARDNER		EXAMINER		
Washington Harbour 3000 K Street, N.W., Suite 500			GOLDBERG, JEANINE ANNE		
Washington, DC 20007-5109			ART UNIT	PAPER NUMBER	
			1634 DATE MAILED: 08/07/2002	1/	

Please find below and/or attached an Office communication concerning this application or proceeding.



# Office Action Summary

Application No.

Jeanine A Goldberg

09/824,567



Applicant(s)

MURDIN ET AL.

Examiner

	l

Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply** 

# A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE $\underline{3}$ MONTH(S) FROM

- THE MAILING DATE OF THIS COMMUNICATION.

  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days and the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will be a few or state of the statutory minimum of thirty (30) days will

- Any re	period for reply is specified above, the maximum see to reply within the set or extended period for repleply received by the Office later than three months dipatent term adjustment. See 37 CFR 1.704(b).	biaitutory pe	eriod Will apply and Wi	ll expire SIX (	n of thirty (30) days will be considered tim 6) MONTHS from the mailing date of this ome ABANDONED (35 U.S.C.§ 133). even if timely filed, may reduce any	∍ly. communication.
1) 🖂	Responsive to communication (a)	سد اممان	40.4.4.0000			
2a) [	Responsive to communication(s) f This action is <b>FINAL</b> .		·· <del>·</del>			
			This action is			
3) Disposition	Since this application is in condition closed in accordance with the practon of Claims	n for all ctice und	lowance except der <i>Ex parte Qı</i>	t for forma uayle, 193	al matters, prosecution as to t 5 C.D. 11, 453 O.G. 213.	he merits is
4)🖂	Claim(s) 1-38 is/are pending in the	applica	ition.			
	a) Of the above claim(s) <u>15-18,20-</u>			awn from	consideration	
	Claim(s) is/are allowed.				ornaldolation,	
6)🛛 (	Claim(s)	e reject	ed.			
	Claim(s) is/are objected to.	,				
	Claim(s) are subject to restric	ction an	d/or election re	auiremen	•	
Application	on Papers			quilonien	ι.	
9) <u> </u>	he specification is objected to by the	e Exam	iner.			
	he drawing(s) filed on is/are:			bjected to	by the Examiner	
	Applicant may not request that any obj	jection to	the drawing(s) b	pe held in a	bevance. See 37 CFR 1 85(a)	
11) 🗌 TI	he proposed drawing correction filed	d on	is: a)∐ apı	proved b)	disapproved by the Examin	er
	If approved, corrected drawings are red	quired in	reply to this Office	ce action.		J1.
12)∐ Ti	he oath or declaration is objected to					
Priority un	nder 35 U.S.C. §§ 119 and 120					
13) 🗌 🛚 A	Acknowledgment is made of a claim	for fore	ign priority und	er 35 U.S	.C. § 119(a)-(d) or (f)	
a)[_	All b) Some * c) None of:		•		1-13 1 10(a) (a) of (i).	,
1	. Certified copies of the priority	docume	ents have been	received.		
	. Certified copies of the priority					
3	. Copies of the certified copies of	of the pr	riority documen	ts have h	een received in this Notional	Stage
* Se	e the attached detailed Office action	n for a li	st of the certifie	ule 17.2(a ed copies	a)). not received.	
14)⊠ Acl	knowledgment is made of a claim fo	r dome:	stic priority und	ler 35 U.S	.C. § 119(e) (to a provisional	application)
a) [	☐ The translation of the foreign lang knowledgment is made of a claim fo	guage p	provisional anni	ication ha	s hash received	apphounoriy.
Attachment(s	)	A GUITTE	one phonty und	161 33 U.S	o.c. 99 120 and/or 121.	
	of References Cited (PTO-892)		41	, m		
) Notice o	of Draftsperson's Patent Drawing Review (PT	O-948)	4, 5)		ew Summary (PTO-413) Paper No(s	

٠,	$\sim$	Monce of	References	Cited	(PT	O-892
					٠	,

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.9.

6) Other:

Art Unit: 1634

## **DETAILED ACTION**

1. This action is in response to the papers filed July 16, 2002. Currently, claims 1-38 are pending. Claims 15-18, 20-34, 37 have been withdrawn as drawn to non-elected subject matter.

#### Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 10 is acknowledged.

The response argues that there is no serious burden for examination of the application as a whole. The examiner has indicated that there is a burden based not only on the divergent classification of each of the groups, but also to separate search in the art.

Claims 15-18, 20-34, 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 15-18, 20-34, 37 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1634

## **Priority**

3. This application claims priority to provisional application 60/194,464, filed April 4, 2000.

## **Drawings**

- 4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
- 5. Figure 2 contains sequences which have not been identified either by SEQ ID NO: in the figure or in the figure legend.

# Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

# Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-14, 19, 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1634

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to variant nucleic acids of SEQ ID NO: 1 and nucleic acids encoding SEQ ID NO: 1.

The specification teaches a single nucleotide sequence, namely an open reading frame (ORF) encoding the Chlamydial myosin ATP-binding cassette from the *C. pneumoniae* genome.

The claims are drawn to nucleic acids which are 75% identical with SEQ ID NO: 2 and have improved immunogenicity. The specification has not described which nucleic acids which are 75% identical with nucleic acids encoding SEQ ID NO: 2 have improved immunogenicity. The specification has not described any regions within the nucleic acids which yield improved immunogenicity. The specification has not described how to modify SEQ ID NO: 2 to obtain polypeptides encoding nucleic acids with improved immunogenicity. Waterfield et al (Genbank Accession Number AQ0990639, August 2000) teaches a nucleic acid which encodes an immunogenic fragment of SEQ ID NO: 2 which is at least 75% identical with the immunogenic fragment of SEQ ID NO: 2. Specifically, amino acids 104-115 of SEQ ID NO: 2 encode the nucleic acid positions 447-482 of Waterfield for 10/12 amino acids, greater than 75%. The nucleic acids is from *Photorhabdus luminescens*. The instant specification has not described the nucleic acids which was taught by Waterfield, however, the claims encompass such a nucleic acid.

Art Unit: 1634

The specification does not provide any description for any nucleic acid which minimally encodes 12 amino acids from SEQ ID NO :2. The specification has not described a representative number of sequences which minimal contain 38 nucleotides of SEQ ID NO: 1. The claims broadly encompass any nucleic acids which contains only 38 nucleotides of SEQ ID NO: 1. These nucleic acids may be from any species or genus. These nucleic acids may have any function or activity. These nucleic acids may be of any length. These nucleic acids may be variation or mutants of SEQ ID NO: 1, which have not been described. The 38 nucleotides of SEQ ID NO: 1 or a nucleic acid which encodes at least 12 amino acids from SEQ ID NO: 2 is not a representative structure for the genus of nucleic acids encompassed by the claims.

The specification has not described homolog of SEQ ID NO: 1 (Claim 13, 14). The specification discloses only one allele within the scope of the genus of homologs, namely SEQ ID NO: 1. There is no description of the regions within the sequences which are conserved among the homologs. The general knowledge in the art concerning homologs does not provide any indication of how the structure of one homolog is representative of unknown homologs. The nature of homologs is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the homologs of the genus and is insufficient to support the claims.

Art Unit: 1634

The specification has not described the structure of any ATP-binding cassette from Chlamydia. Only taught one from pneumonia. The claim as written does not provide both a structure and function for the ATP-binding cassette from Chlamydia. Moreover, as provided in the specification, bacterial species such as *C. pneumoniae*, is usually represented by a variety of strains that differ from each other by minor allelic variations (page 15). Since the specification has asserted that there is variation within *C. pneumoniae*, it follows that there would be more variation over the entire genus of Chlamydia. Therefore, the specification has not described a representative number of ATP-binding cassettes from Chlamydia.

## Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7, 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO: 1 and nucleic acids encoding SEQ ID NO: 2, does not reasonably provide enablement for variants of SEQ ID NO: 1 and variants of nucleic acids encoding SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Art Unit: 1634

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The specification teaches a single nucleotide sequence, namely an open reading frame (ORF) encoding the Chlamydial myosin ATP-binding cassette from the *C. pneumoniae* genome.

The claims are drawn to nucleic acids which are 75% identical with SEQ ID NO: 2 and have improved immunogenicity. The specification has not taught which nucleic acids which are 75% identical with nucleic acids encoding SEQ ID NO: 2 have improved immunogenicity. The specification has not directed the skilled artisan to any regions within the nucleic acids which yield improved immunogenicity. The specification has not taught how to modify SEQ ID NO: 2 to obtain polypeptides encoding nucleic acids with improved immunogenicity. Waterfield et al (Genbank Accession Number AQ0990639, August 2000) teaches a nucleic acid which encodes an immunogenic fragment of SEQ ID NO: 2 which is at least 75% identical with the immunogenic fragment of SEQ ID NO: 2. Specifically, amino acids 104-115 of SEQ ID NO: 2 encode the nucleic acid positions 447-482 of Waterfield for 10/12 amino acids, greater than 75%. The nucleic acids is

Art Unit: 1634

from *Photorhabdus Iuminescens*. The instant specification has not taught how to use the nucleic acids which was taught by Waterfield, however, the claims encompass such a nucleic acid.

The specification does not provide how to use any nucleic acid which minimally encodes 12 amino acids from SEQ ID NO:2. The specification has not described a representative number of sequences which minimal contain 38 nucleotides of SEQ ID NO: 1. The claims broadly encompass any nucleic acids which contains only 38 nucleotides of SEQ ID NO: 1. These nucleic acids may be from any species or genus. These nucleic acids may have any function or activity. These nucleic acids may be of any length. These nucleic acids may be variation or mutants of SEQ ID NO: 1, which have not been described. The 38 nucleotides of SEQ ID NO: 1 or a nucleic acid which encodes at least 12 amino acids from SEQ ID NO: 2 is not a representative structure for the genus of nucleic acids encompassed by the claims. Therefore, the skilled artisan would not know how to make or use the claimed nucleic acids.

## Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3-14, 19, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1634

A) Claims 1, 3-12, 19 are indefinite over the recitation "(c) a polypeptide of (a) or (b) which as been modified to improve its immunogenicity, wherein said modified polypepetide is at least 75% identical in amino acid sequence", in claim 1, because it is unclear whether the claim is allowing for any polypeptide which is 75% identical with SEQ ID NO: 2 or whether the claim is requiring a polypeptide which is 75% identical with SEQ ID NO: 2 which may be further modified.

- B) Claims 13 and 14 are indefinite over the recitation stringent conditions. This term in claims 13 and 14 is a relative term which means different things to different skilled artisans in the art. The specification has provided not exact definition for stringent conditions in the specification. The specification has provided, on page 17, several definitions for stringent conditions.
- C) Claim 36 is indefinite over the recitation "nucleic acid molecule of SEQ ID NO: 3 or 4" because it is unclear whether the claim is open or closed language. "Of" is not generally accepted as either open or closed language. Applicants are requested to clarify whether the claim is directed to nucleic acid sequences comprising SEQ ID NO: 3 or 4 OR consisting of SEQ ID NO: 3 or 4.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1634

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 13, 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Pat. 5,474,796, December 1995).

This rejection is directed to the probes and primers of Claim 13 and 14 which are 10 nucleotides in length.

Brennan teaches an array which contains oligonucleotides having 10 nucleotides each (col. 9, lines 47-50). Every possibly permutation of the 10-mer oligonuleotide is provided. Since Brennan teaches every possibly permutation, Brennan teaches nucleic acid probes of 10 nucleotides in length which hybridize to SEQ ID NO: 1 under stringent conditions.

11. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalman et al. (Genbank Accesion Number AE001606, March 15, 1999).

It is noted that the IDS states that the publication date of the reference is March 15, 1999.

Art Unit: 1634

The nucleic acid of Kalman contains instant SE QID NO: 1. Nucleotides 953-2751 of Kalman is 100% identical with SEQ ID NO: 1, nucleotides 1-1799. The nucleic acid of Kalman is from *Chlamydophila pneumoniae* CWL029. The nucleic acid of Kalman encodes SEQ ID NO: 2. Nucleotides 1053-2648 of Kalman encode amino aicds 1-532 of SEQ ID NO: 2, all of SEQ ID NO: 2. Therefore, since Kalman teaches every limitation of the claims, Kalman anticipates the claimed invention.

12. Claims 1-14, 19, 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Griffais et al (WO 99/27105, June 3, 1999).

Griffais et al. (herein referred to as Griffais) teaches *Chlamydia pneumoniae* genomic sequence. Griffais teaches a nucleic acid molecule which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID NO: 2 polypeptide. The nucleic acid of Griffais encodes a polypepetide which is 99.812% identical as instant SEQ ID NO: 2 (see attached alignment). The nucleic acid molecule of Griffais contains a single added T nucleotide following amino acid 513 and before amino acid 514 (limitations of Claim 1 b, c, 38). Griffais teaches a nucleic acid comprising at least 38 consecutive nucleotides from SEQ ID NO: 1 (namely 1210 consecutive nucleotides)(limitations of Claim 2 c). The nucleic acid of Griffais is 99.3% identical to SEQ ID NO: 1 (limitations of Claim 2 d)(see attached alignment). Griffais teaches antisense nucleic acid sequences of SEQ ID NO: 1 (page 55, lines 14-25)(limitations of Claim 3). The antisense nucleic acids are complementary to at least a portion of an RNA transcript of a polynucleotide sequence in SEQ ID NO: 1. Moreover,

Art Unit: 1634

Griffais teaches that the polypeptides may be expressed as fusion or chimeric protein products. A chimeric product can be made by ligating the appropriate nucleic acid sequences encoding the desired amino acid sequences to each other by methods known in the art, in the proper coding frame (page 54, lines 21-28)(limitations of Claim 4, 5). Griffais teaches that vectors comprise the elements necessary to allow the expression and/or the secrition of said nucleotide sequences in a given host cell (page 51, lines 22-30). The vector should comprise a promoter, signals for initiation and for termination of translation as well as appropriate regions for regulation of transcription (page 51, lines 22-30)(limitations of Claim 7). Griffais teaches immunogenic or vaccine compositions that comprise DNA immunogenic or vaccine compositions comprising polynucleotide sequences (page 69, lines 13-16)(limitations of Claim 8, 9). Griffais teaches that a vaccine composition will be preferably in combination with a pharmaceutically acceptable vehicle and one or more appropriate immunity adjuvants (page 70, lines 32-34)(limitations of Claim 6, 10-11). Griffais teaches host cells may be eukaryotic or prokaryotic systems such as bacterial cells, yeast cells and animal cells (page 54, lines 1-5)(limitations of Claim 12). Griffais teaches culturing cells under conditions to allow replication and/or expression of the transfected nucleotide sequence (page 53)(limitations of Claim 19). Griffais teaches nucleic acid primers and probes which are 20 nucleotides long and at least 100 nucleotides long, respectively (pages 46-47)(limitations of Claim 13, 14).

The pharmaceutical composition claims, 10-11, are directed to compositions, because the pharmaceutical language recited in the claims does not impart any

Art Unit: 1634

particular or new feature, this is interpreted as an "intended use". The composition has no other components other than the nucleic acid and a pharmaceutically acceptable carrier. Nucleic acids are routinely stored in buffers that would be pharmaceutically acceptable.

Therefore, since Griffais teaches each limitation of the claimed invention, Griffais anticipates the claimed invention.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1634

14. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffais et al (WO 99/27105, June 3, 1999) in view of Murdin et al (US Pat. 6,403,101, June 11, 2002).

Griffais et al. (herein referred to as Griffais) teaches Chlamydia pneumoniae genomic sequence. Griffais teaches a nucleic acid molecule which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID NO: 2 polypeptide. The nucleic acid of Griffais encodes a polypepetide which is 99.812% identical as instant SEQ ID NO: 2. The nucleic acid molecule of Griffais contains a single added T nucleotide following amino acid 513 and before amino acid 514 (limitations of Claim 1 b, c, 38). Griffais teaches a nucleic acid comprising at least 38 consecutive nucleotides from SEQ ID NO: 1 (namely 1210 consecutive nucleotides)(limitations of Claim 2 c). The nucleic acid of Griffais is 99.3% identical to SEQ ID NO: 1 (limitations of Claim 2 d). Griffais teaches antisense nucleic acid sequences of SEQ ID NO: 1 (page 55, lines 14-25)(limitations of Claim 3). The antisense nucleic acids are complementary to at least a portion of an RNA transcript of a polynucleotide sequence in SEQ ID NO: 1. Moreover, Griffais teaches that the polypeptides may be expressed as fusion or chimeric protein products. A chimeric product can be made by ligating the appropriate nucleic acid sequences encoding the desired amino acid sequences to each other by methods known in the art, in the proper coding frame (page 54, lines 21-28)(limitations of Claim 4, 5). Griffais teaches that vectors comprise the elements necessary to allow the expression and/or the secrition of said nucleotide sequences in a given host cell (page 51, lines 22-30). The vector

Art Unit: 1634

should comprise a promoter, signals for initiation and for termination of translation as well as appropriate regions for regulation of transcription (page 51, lines 22-30)(limitations of Claim 7). Griffais teaches immunogenic or vaccine compositions that comprise DNA immunogenic or vaccine compositions comprising polynucleotide sequences (page 69, lines 13-16)(limitations of Claim 8, 9). Griffais teaches that a vaccine composition will be preferably in combination with a pharmaceutically acceptable vehicle and one or more appropriate immunity adjuvants (page 70, lines 32-34)(limitations of Claim 6, 10-11). Griffais teaches host cells may be eukaryotic or prokaryotic systems such as bacterial cells, yeast cells and animal cells (page 54, lines 1-5)(limitations of Claim 12). Griffais teaches culturing cells under conditions to allow replication and/or expression of the transfected nucleotide sequence (page 53)(limitations of Claim 19). Griffais teaches nucleic acid primers and probes which are 20 nucleotides long and at least 100 nucleotides long, respectively (pages 46-47)(limitations of Claim 13, 14).

Griffais does not specifically teach expression plasmid pCACPNM209 nor primers for amplifying the genomic DNA for insertion into the plasmid.

However, Murdin teaches designing an expression plasmid using the eukaryotic expression vector pCA/Myc-His (example 2, col. 40, lines 20-50). Murdin teaches using the Invitrogen plasmid and restricting with Spel and BamHI to remove the CMV promoter. The fragments were ligated together to produce plasmid. The Notl/BamHI restricted PCR fragment containing the *C. pneumoniae* gene was ligated into the NotI and BamHI restricted plasmit pCA/Myc-His to produce the resulting plasmid. Murdin

Art Unit: 1634

teaches 5' and 3' primers which include a Notl restriction site which is identical to SEQ ID NO: 3 Notl restriction site and target sequence. SEQ ID NO: 4 of the instant application contains the same BamHI restriction site and sequence encoding the gene.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have inserted the nucleic acid of Griffais into the expression plasmid of Murdin to generate the expression plasmid pCACPNM209. The ordinary artisan would have recognized that placing a known nucleic acid into a known expression plasmid taught in the art was routine. The art teaches all of the necessary components of the plasmid and the ordinary artisan would have been motivated to have chosen any known expression system as taught by Murdin to express the nucleic acid of Griffais. Griffais superficially teaches that any of the standard methods known to those skilled in the art for the insertion of DNA fragments into a vector may be used to construct expression vectors. The expression vector of Murdin was one of those known in the art. Therefore, placing the nucleic acid of Griffais into the expression vector system of Murdin would have been obvious given the teachings in the art for generation of expression vector systems.

Moreover, the ordinary artisan would have been motivated to have designed 5' and 3' primers to enable cloning of the gene into the expression system. The ordinary artisan would have been motivated to have used the NotI restriction site in the 5' primer and the BamHI restriction site in the 3' primer to facilitate insertion of the nucleic acid into the expression vector. Therefore, the ordinary artisan would have designed the two PCR primers with restriction sites and target sequences as taught by Murdin.

Page 17

Therefore, designing SEQ ID NO: 3 and 4 would have been obvious to the ordinary artisan given the teachings of Griffais in view of the teachings of Murdin.

### Conclusion

## 15. No claims allowable over the art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg August 5, 2002

> LISA B. ARTHUR PRIMARY EXAMINER GROUP 1<del>800</del>-/600